Of the monoclonal antibodies produced, the monoclonal antibody designated mAB DAS-1 gave the highest reactivity in the ELISA. The monoclonal antibody mAB DAS-1 was further purified by subcloning. The hybridoma secreting monoclonal antibody mAB DAS-1 is on deposit with the American Type Culture Collection, 10801 University Blvd., Manassas, VA 20110-2209, where it was received April 16, 1987 and catalogued as ATCC #HB9397.

IN THE CLAIMS

Please amend claims 1-3, 6-7, 9-13, 16, 19 and 20, as follows and shown in both the attached Clean Set of Claims and Marked Up Version to Show Amendments:

1. [Once Amended] An in vitro immunoassay method for diagnosing human colonic type gastric intestinal metaplasia which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human colonic type gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen; and

(b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human colonic type gastric intestinal metaplasia.

2. [Once Amended] The method according to claim 1, wherein the human gastric intestinal metaplasia antigen is colon epithelial specific protein.

3. [Once Amended] The method according to claim 1, wherein the antibody or fragment is directly attached to a detectable label.

6. [Once Amended] The method according to claim 5, wherein the immunoperoxidase staining comprises:

(a) deparaffinizing the gastric tissue by heating;

(b) immersing the deparaffinized tissue in xylene;

(c) rehydrating the tissue in decreasing concentrations of alcohol;

(d) washing the rehydrated tissue in neutral PBS;

(e) reducing the aldehydes of the washed tissue of step (d);

(f) reacting the tissue with normal goat serum, the monoclonal antibody, biotinylated goat anti-mouse antibody and avidin-biotin-peroxidase complex;

(g) treating the reacted tissue with diaminobenzidine;

(h) washing the diaminobenzidine-treated tissue;

(i) staining the washed tissue of step (h) with hematoxylin, eosin or both; and

(o) examining the stained tissue under a microscope to detect the presence of immunoreactivity.

7. [Once Amended] The method according to claim 6, which further comprises the step of trypsinizing the gastric tissue after reducing the aldehydes in the tissue but before reacting the tissue with the goat serum, monoclonal antibody, biotinylated goat anti-mouse antibody and avidin-biotin-peroxidase complex.

9. [Once Amended] The method according to claim 1, further comprising the step of performing a negative control assay on a negative control sample to detect cells of human colonic type gastric intestinal metaplasia present in the negative control sample and comparing results of the assay in (b) with the results of the negative control assay, wherein the presence of human colonic type gastric intestinal metaplasia cells in the assay in (b) above the presence of human colonic type gastric intestinal metaplasia cells in the negative control assay indicates a positive diagnosis of human colonic type gastric intestinal metaplasia.

10. [Once Amended] The method according to claim 1, further comprising the step of performing a positive control assay on a positive control sample to detect human cells of colonic type gastric intestinal metaplasia present in the positive control sample.

11. [Once Amended] An in vitro immunoassay method for screening for human colonic type gastric intestinal metaplasia, wherein reactivity with DAS-1 is indicative of a predisposition for gastric carcinoma, which comprises the steps of:

(a) contacting a gastric tissue sample of a subject suspected of having human colonic type gastric intestinal metaplasia cells with the monoclonal antibody DAS-1, or a fragment thereof, which monoclonal antibody is produced by the hybridoma deposited under ATCC accession number HB 9397 and which reacts with human gastric intestinal metaplasia antigen; and

(b) detecting immunoreactivity between the gastric tissue and the monoclonal antibody, such immunoreactivity indicating a positive diagnosis of human colonic type gastric intestinal metaplasia.

12. [Once Amended] The method according to claim 11, wherein the human gastric intestinal metaplasia antigen is colon epithelial specific protein.

13. [Once Amended] The method according to claim 11, wherein the antibody or fragment is directly attached to a detectable label.

16. [Once Amended] The method according to claim 15, wherein the immunoperoxidase staining comprises:

(a) deparaffinizing the gastric tissue by heating;

(b) immersing the deparaffinized tissue in xylene;

(c) rehydrating the tissue in decreasing concentrations of alcohol;

(d) washing the rehydrated tissue in neutral PBS;

(e) reducing the aldehydes of the washed tissue of step (d);

(f) reacting the tissue with normal goat serum, the monoclonal antibody, biotinylated goat anti-mouse antibody and avidin-biotin-peroxidase complex;

(g) treating the reacted tissue with diaminobenzidine;

(h) washing the diaminobenzidine-treated tissue;

(i) staining the washed tissue of step (h) with hematoxylin, eosin or both; and

examining the stained tissue under a microscope to detect the presence of immunoreactivity.

17. [Once Amended] The method according to claim 16, which further comprises the step of trypsinizing the gastric tissue after reducing the aldehydes in the tissue but before reacting the tissue with the goat serum, monoclonal antibody, biotinylated goat anti-mouse antibody and avidin-biotin-peroxidase complex.

19. [Once Amended] The method according to claim 16, further comprising the step of performing a negative control assay on a negative control sample to detect cells of human colonic type gastric intestinal metaplasia present in the negative control sample and comparing results of the assay in (b) with the results of the negative control assay,

wherein the presence of human colonic type gastric intestinal metaplasia cells in the assay in (b) above the presence of human colonic type gastric intestinal metaplasia cells in the negative control assay indicates a positive diagnosis of human colonic type gastric intestinal metaplasia.

20. [Once Amended] The method according to claim 16, further comprising the step of performing a positive control assay on a positive control sample to detect human cells of colonic type gastric intestinal metaplasia present in the positive control sample.